

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE
in its capacity as elected Office

Date of mailing (day/month/year) 20 March 2001 (20.03.01)	
International application No. PCT/US00/18249	Applicant's or agent's file reference 235.00300201
International filing date (day/month/year) 30 June 2000 (30.06.00)	Priority date (day/month/year) 01 July 1999 (01.07.99)
Applicant FAYRER-HOSKEN, Richard et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:

31 January 2001 (31.01.01)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Juan Cruz Telephone No.: (41-22) 338.83.38
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PATENT COOPERATION TREATY

PCT

From the INTERNATIONAL BUREAU

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

To:

SANDBERG, Victoria, A.
Mueting, Raasch & Gebhardt, P.A.
P.O. Box 581415
Minneapolis, MN 55458-1415
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year) 30 août 2001 (30.08.01)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference 235.00300201	
International application No. PCT/US00/18249	International filing date (day/month/year) 30 juin 2000 (30.06.00)

1. The following indications appeared on record concerning:

☒ the applicant ☒ the inventor ☐ the agent ☐ the common representative

Name and Address

FAYRER-HOSKEN, Richard
P.O. Box 27
Winterville, GA 30683
United States of America

State of Nationality

US

State of Residence

US

Telephone No.

Facsimile No.

Teleprinter No.

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐ the person ☐ the name ☐ the address ☒ the nationality ☐ the residence

Name and Address

FAYRER-HOSKEN, Richard
P.O. Box 27
Winterville, GA 30683
United States of America

State of Nationality

GB

State of Residence

US

Telephone No.

Facsimile No.

Teleprinter No.

3. Further observations, if necessary:
Correction of nationality.

4. A copy of this notification has been sent to:

☒ the receiving Office ☐ the designated Offices concerned
☐ the International Searching Authority ☒ the elected Offices concerned
☒ the International Preliminary Examining Authority ☐ other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

Anman QIU

Facsimile No.: (41-22) 740.14.35

Telephone No.: (41-22) 338.83.38

PCT

REC'D 11 OCT 2001

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

WIPO PCT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 235.00300201	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US00/18249	International filing date (day/month/year) 30/06/2000	Priority date (day/month/year) 01/07/1999
International Patent Classification (IPC) or national classification and IPC A61K38/00		
Applicant THE UNIVERSITY OF GEORGIA RESEARCH FOUNDATION, INC		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 10 sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☒ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 31/01/2001	Date of completion of this report 09.10.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Fayos, C Telephone No. +49 89 2399 2180 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/US00/18249

1. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-29 as originally filed

Claims, No.:

1-40 as originally filed

Drawings, sheets:

1/3-3/3 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/US00/18249

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

II. Priority

1. ☐ This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:

☐ copy of the earlier application whose priority has been claimed.

☐ translation of the earlier application whose priority has been claimed.

2. ☐ This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid.

Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:
see separate sheet

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 1-3, 12-28 and 30-40 (industrial applicability) and 4-11 (completely), 12-28 (partially) and 29 (completely).

because:

☒ the said international application, or the said claims Nos. 1-3, 12-28 and 30-40 (industrial applicability) relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/US00/18249

- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the said claims Nos. 4-11 (completely), 12-28 (partially) and 29 (completely).

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.
- ☐ the computer readable form has not been furnished or does not comply with the standard.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☐ paid additional fees.
- ☐ paid additional fees under protest.
- ☒ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
- ☒ not complied with for the following reasons:
see separate sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☐ all parts.
- ☒ the parts relating to claims Nos. 1-3, 12-28 (partially) and 30-40.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims 1-3, 12-28 (partially) and 30-40
	No:	Claims -

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/US00/18249

Inventive step (IS)

Yes: Claims -

No: Claims 1-3, 12-28 (partially) and 30-40

Industrial applicability (IA)

Yes: Claims 1-3, 12-28 (partially) and 30-40 see separate sheet

No: Claims -

2. Citations and explanations
see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US00/18249

Re Item II

Priority

- 1- The priority date (01.07.1999) of the present application is valid. Hence, D1 is not prior art in this case.

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

- 2- Claims 1-3, 12-28 and 30-40 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).
- 3- No opinion will be formulated on the subject matter of claims 4-11 (completely), 12-28 (partially) and 29 (completely) (see item IV below).

Re Item IV

Lack of unity of invention

- 4- The International Search Authority has raised an objection of unity of invention (Rules 13.1, 13.2 and 13.3 PCT - see extra sheet ISA206).
 - 4.1- Since no required additional search fees were timely paid by the applicant, the international search report has been restricted to the invention first mentioned in the claims, i. e. claims 1-3, claims 12-28 (partially) and claims 30-40.
 - 2.2- Hence, this written opinion will be restricted to the subject matter that has been searched, i. e. claims 1-3, claims 12-28 (partially) and claims 30-40.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US00/18249

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

5- Reference is made to the following documents:

- D1: WO 00 37100 A (DALHOUSIE UNIVERSITY) 29 June 2000 (2000-06-29)
- D2: WO 93 25231 A (DALHOUSIE UNIVERSITY) 23 December 1993 (1993-12-23)
- D3: US-A-5 656 488 (CURTISS) 13 August 1997 (1997-08-13)
- D4: P. WILLIS ET AL.: 'Equine immunocontraception using porcine zona pellucida' J. EQUINE VET. SCI., vol. 14, no. 7, 1994, pages 364-370, XP000978916
- D5: Y. TAKEUCHI ET AL.: 'A 42kd glycoprotein from chicken egg envelope and avian homolog of the ZPC family in mammalian zona pellucida' EUR. J. BIOCHEM., vol. 260, 1999, pages 736-742, XP000978737

5.1- Additional documents (a copy of these documents has been sent to the applicant):

- D6: Thian J et al. Xenopus laevis sperm receptor gp69/64 glycoprotein is a homolog of the mammalian sperm receptor ZP2. Proc Natl Acad Sci USA 1999 Feb. 2;96(3):829-34 (Abstract PUBMED).
- D7: Miura T et al. Two testicular cDNA clones suppressed by gonadotropin stimulation exhibit ZP-2 and ZP3-like structures in Japanese eel. Mol Reprod Dev 1998 Nov; 51(3):235-42 (Abstract PUBMED).
- D8: Howarth B. Avian sperm-egg interaction: perivitelline layer possesses receptor activity for spermatozoa. Poult Sci 1990 Jun; 69(6):1012-5 (Abstract PUBMED).

NOVELTY - Art. 33 (1) and (2) PCT

6- **Claims 1-3, 12-28 (partially) and 30-40 appear to be novel over the prior art cited in the search report.**

6.1- The novel features are:

- a method of controlling reproduction in an organism selected from the group consisting of a bird, a fish, a reptile, an amphibian, an insect, an arachnid and

- an oocyte-producing parasite (see claim 1), and
- a method for pest management (see claim 30).

INVENTIVE STEP - Art. 33 (1) and (3) PCT

- 7- Claims 1-3, 12-28 (partially) and 30-40 lack inventive step for the reasons stated below.**

- 7.1- The closest prior art is represented by any of D2-D4 which all relate to the use of a zona pellucida protein for use in immunocontraception.**

In particular, D2 discloses a vaccine for the immunocontraception of mammals, consisting of zona pellucida antigens (glycoproteins - porcine oocyte zona pellucida protein ZP3 see p 3 lines 24-28 and p 4 lines 11-33) and an adjuvant (such as Freund's adjuvant - see claims). The zona pellucida antigen may also be purified from oocytes or alternatively, a recombinant ZP antigen may be used. Furthermore, D2 explains the immunocontraception by the binding of anti-porcine ZP antibodies to seal oocytes (p 18 lines 19-23).

D3 discloses a vaccine for the immunocontraception of horses (can be assimilated as a pest in view of the , consisting of porcine zona pellucida, combined with STDCM (see abstract and discussion).

D4 mentions (c 2 line 56 - c 3 line 8 and example 11) that rabbits, dogs and monkeys immunized with porcine ZP-3 had abnormal ovarian function and loss of follicles. However, parenteral immunization of mice with a ZP-3 B cell epitope fused to keyhole limpet hemocyanin, induces complete and reversible infertility in Swiss mice, but ovarian autoimmune disease and complete non reversible infertility of B6AF1 female mice. In Example 11, D4 relates to the construction of recombinant avirulent salmonella expressing murine ZP3 and its use for immunization of animals.

The closest prior art documents differ from the present application in that none of them mentions the use of a zona pellucida protein for the immunocontraception of

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US00/18249

a bird, a fish, a reptile, an amphibian, an insect, an arachnid and an oocyte-producing parasite and its use for pest management.

The technical effect achieved in the present application is the immunocontraception of a bird, a fish, a reptile, an amphibian, an insect, an arachnid and an oocyte-producing parasite and pest management.

The objective problem posed in the present application is to provide alternative uses for the well known (see any of D2-D4) immunocontraception method consisting of zona pellucida proteins.

The solution proposed is the use of a zona pellucida protein for the immunocontraception of a bird, a fish, a reptile, an amphibian, an insect, an arachnid and an oocyte-producing parasite and its use for pest management.

Said solution is obvious, as shown below.

- 7.2- Therefore, in the light of these teachings the skilled man would have extended the teachings of any of D2-D4 to other organisms which produce oocytes, and in particular for pest management.

The features of claims 2-3, 12-28 (partially) and 29-40 are merely some of several straightforward possibilities from which the skilled person would select, in accordance with circumstances and in the light of the teachings of the prior art, without the exercise of inventive skill, in order to provide alternative uses for the well known (see any of D2-D4) immunocontraception method consisting of zona pellucida proteins.

Claims 1-3, 12-28 (partially) and 30-40 lack therefore inventive step.

- 7.3- Note that D5 discloses the identification and cDNA cloning of a 42 kDa glycoprotein from chicken egg-envelope, an avian homolog of the ZPC family glycoproteins in mammalian zona pellucida. The skilled man would have hence expected the vaccine for immunocontraception consisting of zona pellucida antigens to be effective in other groups than mammals, e. g. birds (see also, as a complement, additional documents D6-D8).

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US00/18249

INDUSTRIAL APPLICABILITY - Art. 33 (1) and (4) PCT

- 8- For the assessment of the present claims 1-3, 12-28 and 30-40 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

From the INTERNATIONAL SEARCHING AUTHORITY

PCTNOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT
OR THE DECLARATION

(PCT Rule 44.1)

Art. 19 - 6/25/01
KJM

To: MUETING, RAASCH & GEBHARDT, P.A. Attn. SANDBERG, Victoria A. P.O. Box 581415 Minneapolis, MN 55458-1415 UNITED STATES OF AMERICA

Date of mailing (day/month/year)	25/04/2001
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Applicant's or agent's file reference 235.00300201	FOR FURTHER ACTION See paragraphs 1 and 4 below
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International application No. PCT/US 00/18249	International filing date (day/month/year) 30/06/2000
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Applicant THE UNIVERSITY OF GEORGIA RESEARCH FOUNDATION, INC

1. ☒ The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

Within **19 months** from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within **20 months** from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Carla Louro



NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 235.00300201	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/US 00/ 18249	International filing date (day/month/year) 30/06/2000	(Earliest) Priority Date (day/month/year) 01/07/1999
Applicant THE UNIVERSITY OF GEORGIA RESEARCH FOUNDATION, INC		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 5 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☒ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☒ None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No

.CT/ 0/18249

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K38/17 A01N37/46 A61P15/18

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

CHEM ABS Data, BIOSIS, WPI Data, EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	WO 00 37100 A (DALHOUSIE UNIVERSITY) 29 June 2000 (2000-06-29) the whole document	1-3, 12-14, 16-23, 30-34, 36-38
X	WO 93 25231 A (DALHOUSIE UNIVERSITY) 23 December 1993 (1993-12-23)	1-3, 12-21, 23, 30-38
Y	the whole document -/--	24, 26-28

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

18 January 2001

Date of mailing of the international search report

25. 04. 2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

SKELLY J.M.

PCT/00/18249

Relevant to claim No.	
-----------------------	--

1-3,
17-20,
30,36,37

24,26-28

15

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 00/18249

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

see further information sheet invention group 1.

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-3, 12-28 (partially), 30-40

A method for controlling reproduction in an organism, or a method of pest management comprising administering to an organism an immunogenic composition comprising at least one component selected from the group consisting of (a) a polypeptide comprising a zona pellucida protein or an immunogenic fragment thereof and (b) a polynucleotide comprising a nucleotide sequence encoding a polypeptide comprising a zona pellucida protein or an immunogenic fragment thereof.

2. Claims: 4-9, 12-28 (partially)

A method for treating or preventing a reproductive disorder or disease in an oocyte-producing organism, comprising administering to an organism an immunogenic composition comprising at least one component selected from the group consisting of (a) a polypeptide comprising a zona pellucida protein or an immunogenic fragment thereof and (b) a polynucleotide comprising a nucleotide sequence encoding a polypeptide comprising a zona pellucida protein or an immunogenic fragment thereof.

3. Claims: 10, 11, 12-28 (partially)

A method for controlling behaviour in an oocyte-producing organism, comprising administering to an organism an immunogenic composition comprising at least one component selected from the group consisting of (a) a polypeptide comprising a zona pellucida protein or an immunogenic fragment thereof and (b) a polynucleotide comprising a nucleotide sequence encoding a polypeptide comprising a zona pellucida protein or an immunogenic fragment thereof.

4. Claim : 29

A method for affecting the reproductive system of an oocyte-producing organism, comprising administering to an organism an immunogenic composition comprising at least one component selected from the group consisting of (a) a polypeptide comprising a zona pellucida protein or an immunogenic fragment thereof and (b) a polynucleotide comprising a nucleotide sequence encoding a polypeptide comprising a zona pellucida protein or an immunogenic fragment thereof.

Patent Family Annex

Information on patent family members

International Application No

PCT/US 00/18249

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0037100	A	29-06-2000	AU 1765300 A	12-07-2000
WO 9325231	A	23-12-1993	AU 4303493 A	04-01-1994
			CA 2137363 A	23-12-1993
			US 5736141 A	07-04-1998
US 5656488	A	12-08-1997	AT 177787 T	15-04-1999
			AU 9094191 A	25-06-1992
			CA 2096529 A	22-05-1992
			CN 1072454 A	26-05-1993
			DE 69131014 D	22-04-1999
			DE 69131014 T	07-10-1999
			EP 0558631 A	08-09-1993
			ES 2133311 T	16-09-1999
			IL 100121 A	15-06-1998
			WO 9209684 A	11-06-1992
			ZA 9109213 A	26-08-1992

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

SANDBERG, Victoria A.
MUETING, RAASCH & GEBHARDT, P.A.
P.O. Box 581415
Minneapolis, MN 55458-1415
ETATS-UNIS D'AMERIQUE

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing
(day/month/year) 09.10.2001

Applicant's or agent's file reference
235.00300201

IMPORTANT NOTIFICATION

International application No.
PCT/US00/18249

International filing date (day/month/year)
30/06/2000

Priority date (day/month/year)
01/07/1999

Applicant
THE UNIVERSITY OF GEORGIA RESEARCH FOUNDATION, INC

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

RECEIVED
OCT 21 2001
MUETING AND RAASCH

Name and mailing address of the IPEA/

 European Patent Office
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Tel. +49 89 2399 - 0 Tx: 523656 epmu d
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Authorized officer

Hundt, D



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PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 235.00300201		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US00/18249	International filing date (day/month/year) 30/06/2000	Priority date (day/month/year) 01/07/1999	
International Patent Classification (IPC) or national classification and IPC A61K38/00			
Applicant THE UNIVERSITY OF GEORGIA RESEARCH FOUNDATION, INC			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 10 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none">I <input checked="" type="checkbox"/> Basis of the reportII <input checked="" type="checkbox"/> PriorityIII <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicabilityIV <input checked="" type="checkbox"/> Lack of unity of inventionV <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statementVI <input type="checkbox"/> Certain documents citedVII <input type="checkbox"/> Certain defects in the international applicationVIII <input type="checkbox"/> Certain observations on the international application			
Date of submission of the demand 31/01/2001		Date of completion of this report 09.10.2001	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized officer Fayos, C Telephone No. +49 89 2399 2180 	

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/US00/18249

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-29 as originally filed

Claims, No.:

1-40 as originally filed

Drawings, sheets:

1/3-3/3 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/US00/18249

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

II. Priority

1. ☐ This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:

☐ copy of the earlier application whose priority has been claimed.

☐ translation of the earlier application whose priority has been claimed.

2. ☐ This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid.

Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:
see separate sheet

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 1-3, 12-28 and 30-40 (industrial applicability) and 4-11 (completely), 12-28 (partially) and 29 (completely).

because:

☒ the said international application, or the said claims Nos. 1-3, 12-28 and 30-40 (industrial applicability) relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/US00/18249

- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
 - ☒ no international search report has been established for the said claims Nos. 4-11 (completely), 12-28 (partially) and 29 (completely).
2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:
- ☐ the written form has not been furnished or does not comply with the standard.
 - ☐ the computer readable form has not been furnished or does not comply with the standard.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:
- ☐ restricted the claims.
 - ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☒ neither restricted nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-3, 12-28 (partially) and 30-40.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims 1-3, 12-28 (partially) and 30-40
	No:	Claims -

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/US00/18249

Inventive step (IS)	Yes:	Claims	-
	No:	Claims	1-3, 12-28 (partially) and 30-40
Industrial applicability (IA)	Yes:	Claims	1-3, 12-28 (partially) and 30-40 see separate sheet
	No:	Claims	-

2. Citations and explanations
see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US00/18249

Re Item II

Priority

- 1- The priority date (01.07.1999) of the present application is valid. Hence, D1 is not prior art in this case.

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

- 2- Claims 1-3, 12-28 and 30-40 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).
- 3- No opinion will be formulated on the subject matter of claims 4-11 (completely), 12-28 (partially) and 29 (completely) (see item IV below).

Re Item IV

Lack of unity of invention

- 4- The International Search Authority has raised an objection of unity of invention (Rules 13.1, 13.2 and 13.3 PCT - see extra sheet ISA206).
- 4.1- Since no required additional search fees were timely paid by the applicant, the international search report has been restricted to the invention first mentioned in the claims, i. e. claims 1-3, claims 12-28 (partially) and claims 30-40.
- 2.2- Hence, this written opinion will be restricted to the subject matter that has been searched, i. e. claims 1-3, claims 12-28 (partially) and claims 30-40.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US00/18249

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

5- Reference is made to the following documents:

- D1: WO 00 37100 A (DALHOUSIE UNIVERSITY) 29 June 2000 (2000-06-29)
- D2: WO 93 25231 A (DALHOUSIE UNIVERSITY) 23 December 1993 (1993-12-23)
- D3: US-A-5 656 488 (CURTISS) 13 August 1997 (1997-08-13)
- D4: P. WILLIS ET AL.: 'Equine immunocontraception using porcine zona pellucida' J. EQUINE VET. SCI., vol. 14, no. 7, 1994, pages 364-370, XP000978916
- D5: Y. TAKEUCHI ET AL.: 'A 42kd glycoprotein from chicken egg envelope and avian homolog of the ZPC family in mammalian zona pellucida' EUR. J. BIOCHEM., vol. 260, 1999, pages 736-742, XP000978737

5.1- Additional documents (a copy of these documents has been sent to the applicant):

- D6: Thian J et al. Xenopus laevis sperm receptor gp69/64 glycoprotein is a homolog of the mammalian sperm receptor ZP2. Proc Nati Acad Sci USA 1999 Feb. 2;96(3):829-34 (Abstract PUBMED).
- D7: Miura T et al. Two testicular cDNA clones suppressed by gonadotropin stimulation exhibit ZP-2 and ZP3-like structures in Japanese eel. Mol Reprod Dev 1998 Nov; 51(3):235-42 (Abstract PUBMED).
- D8: Howarth B. Avian sperm-egg interaction: perivitelline layer possesses receptor activity for spermatozoa. Poult Sci 1990 Jun; 69(6):1012-5 (Abstract PUBMED).

NOVELTY - Art. 33 (1) and (2) PCT

6- **Claims 1-3, 12-28 (partially) and 30-40 appear to be novel over the prior art cited in the search report.**

6.1- The novel features are:

- a method of controlling reproduction in an organism selected from the group consisting of a bird, a fish, a reptile, an amphibian, an insect, an arachnid and

- an oocyte-producing parasite (see claim 1), and
- a method for pest management (see claim 30).

INVENTIVE STEP - Art. 33 (1) and (3) PCT

7- Claims 1-3, 12-28 (partially) and 30-40 lack inventive step for the reasons stated below.

7.1- The closest prior art is represented by any of D2-D4 which all relate to the use of a zona pellucida protein for use in immunocontraception.

In particular, D2 discloses a vaccine for the immunocontraception of mammals, consisting of zona pellucida antigens (glycoproteins - porcine oocyte zona pellucida protein ZP3 see p 3 lines 24-28 and p 4 lines 11-33) and an adjuvant (such as Freund's adjuvant - see claims). The zona pellucida antigen may also be purified from oocytes or alternatively, a recombinant ZP antigen may be used. Furthermore, D2 explains the immunocontraception by the binding of anti-porcine ZP antibodies to seal oocytes (p 18 lines 19-23).

D3 discloses a vaccine for the immunocontraception of horses (can be assimilated as a pest in view of the , consisting of porcine zona pellucida, combined with STDCM (see abstract and discussion).

D4 mentions (c 2 line 56 - c 3 line 8 and example 11) that rabbits, dogs and monkeys immunized with porcine ZP-3 had abnormal ovarian function and loss of follicles. However, parenteral immunization of mice with a ZP-3 B cell epitope fused to keyhole limpet hemocyanin, induces complete and reversible infertility in Swiss mice, but ovarian autoimmune disease and complete non reversible infertility of B6AF1 female mice. In Example 11, D4 relates to the construction of recombinant avirulent salmonella expressing murine ZP3 and its use for immunization of animals.

The closest prior art documents differ from the present application in that none of them mentions the use of a zona pellucida protein for the immunocontraception of

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US00/18249

a bird, a fish, a reptile, an amphibian, an insect, an arachnid and an oocyte-producing parasite and its use for pest management.

The technical effect achieved in the present application is the immunocontraception of a bird, a fish, a reptile, an amphibian, an insect, an arachnid and an oocyte-producing parasite and pest management.

The objective problem posed in the present application is to provide alternative uses for the well known (see any of D2-D4) immunocontraception method consisting of zona pellucida proteins.

The solution proposed is the use of a zona pellucida protein for the immunocontraception of a bird, a fish, a reptile, an amphibian, an insect, an arachnid and an oocyte-producing parasite and its use for pest management.

Said solution is obvious, as shown below.

- 7.2- Therefore, in the light of these teachings the skilled man would have extended the teachings of any of D2-D4 to other organisms which produce oocytes, and in particular for pest management.

The features of claims 2-3, 12-28 (partially) and 29-40 are merely some of several straightforward possibilities from which the skilled person would select, in accordance with circumstances and in the light of the teachings of the prior art, without the exercise of inventive skill, in order to provide alternative uses for the well known (see any of D2-D4) immunocontraception method consisting of zona pellucida proteins.

Claims 1-3, 12-28 (partially) and 30-40 lack therefore inventive step.

- 7.3- Note that D5 discloses the identification and cDNA cloning of a 42 kDa glycoprotein from chicken egg-envelope, an avian homolog of the ZPC family glycoproteins in mammalian zona pellucida. The skilled man would have hence expected the vaccine for immunocontraception consisting of zona pellucida antigens to be effective in other groups than mammals, e. g. birds (see also, as a complement, additional documents D6-D8).

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US00/18249

INDUSTRIAL APPLICABILITY - Art. 33 (1) and (4) PCT

- 8- For the assessment of the present claims 1-3, 12-28 and 30-40 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.